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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
12/29/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Response to Arguments

Applicant's arguments filed 12/16/10 have been fully considered but they are not persuasive.

1. Request for Reconsideration of Finality of Office Action:

Applicant respectfully requests the finality of the 7 July 2010 Office Action be withdrawn. MPEP 706.7(a) states: "Under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims, nor based on information submitted in an information disclosure statement filed during the period set forth in 37 C.F.R 1.97(c) with the fee set forth in 37 C.F.R. 1.17(p)." *(emphasis added)*. In accordance with MPEP 706.7(a), Applicant submits: (1) The previous amendment submitted on 23 April 2010 did not necessitate the new 103 rejection using Ulman as primary reference; and (2) Ulman was not based on information submitted in an information disclosure statement filed during the period set forth in 37 C.F.R 1.97(c) with the fee set forth in 37 C.F.R. 1.17(p). Therefore, Applicant should be afforded the opportunity to respond to the new 103 rejection and finality of the 7 July 2010 Office Action should be withdrawn, unless the Application is deemed allowable following this response.

However, in response to Applicant's arguments, the Examiner notes that the Amendment filed 04/23/10 required at least two limitations that were not previously submitted:

1) melting and homogenizing components of the cement matrix and rotigotine in an extruder *without solvent*. The phrase "solvent free" as previously recited in the claims, and the phrase "without solvent" as required in the Amendment filed 04/23/10 are not exactly the same in scope; and

2) the method of claim 18 is a *two-step process*.

Accordingly, for at least the above reasons, the Finality of the Office Action dated 07/07/10 is maintained.

2. Obviousness-type Double Patenting:

Applicant may elect to argue to overcome this ground of rejection or to provide a terminal disclaimer (to the extent necessary) once the present claims have been found to be otherwise allowable and/or once the co-pending application issues as a patent.

Hence, the rejection is maintained.

3. Rejection under 35 U.S.C. §103(a) over Ulman in view of Schollmayer:

Applicant argues that Ulman fails to teach the claimed active agent, rotigotine. Moreover, Ulman is a completely generic document. Ulman teaches no specific agents. Thus, Ulman gives no concrete guidance whatsoever as to which specific bioactive agents are suitable for use in the PSA, let alone a method for incorporating such an agent in the PSA without damaging the agent in the process. Ulman describes that a bioactive agent may be incorporated into the hot-melt pressure sensitive adhesive (p. 5, lines 30-31), but this mere statement does not amount to a teaching of specifically

homogenizing rotigotine and a cement matrix. Furthermore, Ulman's exclusive and express focus is on a hot-meltable adhesive for use with hydrophilic drugs, and rotigotine is a lipophilic drug. Applicant further argues that Ulman and Schollmayer teach substantially incompatible methods for preparing a transdermal system, and thus the cited references are not combinable.

However, Applicant's arguments are not persuasive for the following reasons:

1) Ulman teaches that "hot-melt compositions have been found to be inadequate for the delivery of hydrophilic drugs from transdermal drug delivery system" (page 2, lines 13-15). From this, it is readily apparent that hot-melt compositions are in deed more adequate for the delivery of lipophilic drugs than hydrophilic drugs;

2) the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985);

3) Ulman teaches many advantageous results in using hot-melt PSA over solvent-based PSA (pressure sensitive adhesive), which includes: a) safety, environmental and application considerations; b) hot-melt PSA does not contain solvents which interfere with the addition of other ingredients to be PSA; and c) more useful in medical area. See page 2, lines 5-12;

4) Ulman is cited in view of Schollmayer, which teaches the use of rotigotine in a PSA is desired; and

5) In response to applicant's argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, Schollmayer teaches the desirability for putting rotigotine in a PSA composition. Ulman teaches that hot-melt PSA is better than solvent based PSA for the fact that solvent will interfere with the active agent.

Accordingly, one of ordinary skill in the art would have been motivated to, by routine experimentation prepare a transdermal therapeutic system using the hot-melt PSA process of Ulman over the solvent-based PSA taught by Schollmayer for the delivery of rotigonine. This is because incorporating rotigotine in a PSA is well known in the art. Hence, the 103(a) rejection over Ulman and Schollmayer is maintained.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. TRAN whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. TRAN/
Primary Examiner, Art Unit 1615